

Plaintiffs Teijin Limited (“Teijin Ltd.”), together with its subsidiary Teijin Pharma Limited (“Teijin Pharma Ltd.”) (collectively, “Teijin”), and Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) (collectively, “Plaintiffs”), for their Complaint against Defendants Lupin Limited (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (“LPI”) (collectively “Lupin”), hereby allege as follows:

1. Plaintiff Teijin Ltd. is a Japanese corporation, having a principal place of business at 6-7, Minami-Hommachi 1-chome, Chuo-ku, Osaka 541-8587, Japan.
2. Plaintiff Teijin Pharma Ltd. is a Japanese corporation, having its principal place of business at 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan.
3. Plaintiff Takeda is a Delaware corporation, having its principal place of business at 1 Takeda Parkway, Deerfield, Illinois 60015.
4. Upon information and belief, Lupin Ltd. is a company organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers,

Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. On information and belief, Lupin Ltd. is in the business of, among other things, developing, manufacturing, packaging, and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of its agents and operating subsidiaries, including its wholly-owned subsidiary, LPI. On information and belief, Lupin Ltd. has previously submitted to this Court's jurisdiction. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010); *Senju Pharmaceutical Co., Ltd. v. Lupin Ltd.*, No. 11-cv-00271, D.I. 11 (D. Del. June 6, 2011). Lupin Ltd. has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010); *Senju Pharmaceutical Co., Ltd. v. Lupin Ltd.*, No. 11-cv-00271, D.I. 11 (D. Del. June 6, 2011).

5. Upon information and belief, LPI is a wholly-owned subsidiary and agent of Lupin Ltd. and is a company organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, LPI is the United States marketing and sales agent for Lupin Ltd., and is engaged in the sale and distribution of generic versions of branded pharmaceutical products in the United States, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of its agents. On information and belief, LPI has previously submitted to this Court's jurisdiction. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010); *Senju Pharmaceutical Co., Ltd. v. Lupin Ltd.*, No. 11-cv-00271, D.I. 11 (D. Del. June 6, 2011). LPI has purposefully availed itself of the jurisdiction of this

Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010).

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 6,225,474 (“the ’474 patent” or “the patent-in-suit”). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Ltd. by virtue of, *inter alia*, the fact that Lupin Ltd. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Takeda Pharmaceuticals U.S.A. Inc., a Delaware corporation, having conducted business in Delaware and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over Lupin Ltd. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court has personal jurisdiction over Lupin Ltd. because upon information and belief, Lupin Ltd. regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

10. This Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has previously been sued in this district and has not challenged personal jurisdiction, and Lupin Ltd. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010); *Senju Pharmaceutical Co., Ltd. v. Lupin Ltd.*, No. 11-cv-00271, D.I. 11 (D. Del. June 6, 2011).

11. This Court also has personal jurisdiction over Lupin Ltd. by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

12. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that LPI has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Takeda Pharmaceuticals U.S.A. Inc., a Delaware corporation, having conducted business in Delaware and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over LPI for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

13. This Court has personal jurisdiction over LPI because upon information and belief, LPI regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

14. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that LPI distributes drug products for sale throughout the United States, including in this judicial district.

15. This Court has personal jurisdiction over LPI because LPI has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Cephalon, Inc. v. Lupin Ltd.*, No. 10-cv-00210, D.I. 8 (D. Del. March 31, 2010).

16. This Court also has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

18. On May 1, 2001, the '474 patent, titled "Polymorphs of 2-(3-cyano-4-isobutyloxyphenyl)-4-methyl-5-thiazolecarboxylic acid and method of producing the same," was issued. A copy of the '474 patent is attached as Exhibit A. Teijin Ltd. is the owner of the '474 patent. Teijin Pharma Ltd. and Takeda hold exclusive licenses with respect to the '474 patent.

ACTS GIVING RISE TO THIS ACTION

19. Takeda holds New Drug Application ("NDA") No. 21-856 for oral tablets containing 40 or 80 mg of the active ingredient febuxostat. Takeda markets and sells these tablets in the United States under the brand name "Uloric®."

20. Pursuant to 21 U.S.C. § 355(b)(1), the '474 patent is listed in the FDA's publication titled, Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"), as covering Uloric® or its use.

21. Upon information and belief, Lupin Ltd. submitted ANDA No. 205406 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (“Lupin’s ANDA”). Upon information and belief, Lupin’s ANDA No. 205406 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 40 and 80 mg of febuxostat (“the Lupin Generic Product”) prior to the expiration of the ’474 patent.

22. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Lupin Ltd. certified in ANDA No. 205406 that no valid claim of the ’474 patent will be infringed by the commercial manufacture, use, or sale of the proposed Lupin Generic Product.

23. Plaintiffs received written notification of Lupin’s ANDA No. 205406 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated January 28, 2014 (“Notice Letter”).

24. Lupin Ltd.’s Notice Letter does not deny infringement of claims 1 and 6 of the ’474 patent separate and apart from asserting invalidity.

25. Upon information and belief, Lupin Ltd. will manufacture the Lupin Generic Product and/or API and release the Lupin Generic Product for distribution in the United States.

26. Upon information and belief, LPI will market and sell the Lupin Generic Product in the United States.

27. Lupin’s Notice Letter does not refer to a certification with respect to U.S. Patent No. 5,614,520 (“the ’520 patent”), and does not provide any detailed statement with regard to the ’520 patent. Accordingly, upon information and belief, Lupin’s ANDA No. 205406

contains a “Paragraph III” certification with respect to the ’520 patent pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(III). The expiration date of the ’520 patent is March 25, 2019.

INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 6,225,474

28. Plaintiffs re-allege paragraphs 1-27 as if fully set forth herein.

29. Upon information and belief, Lupin’s submission of ANDA No. 205406 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the ’474 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Lupin Generic Product, if approved by the FDA, prior to the expiration of the ’474 patent, including any applicable exclusivities or extensions, would infringe the ’474 patent under 35 U.S.C. § 271.

31. Upon information and belief, Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin Ltd.’s ANDA No. 205406 be a date that is not earlier than the expiration of the patent term including any extension granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the ’474 patent to which Plaintiffs are or become entitled.

32. Plaintiffs will be irreparably harmed by Lupin’s infringing activities, unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

33. Upon information and belief, Lupin was aware of the existence of the ’474 patent and was aware that the filing of its ANDA and certification with respect to the ’474 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Lupin has infringed the '474 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205406 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '474 patent, including any applicable exclusivities or extensions;
- C. That Lupin, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Lupin Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '474 patent prior to its expiration, including any exclusivities or extensions;
- D. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and
- E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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